POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

Good Review Practices

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PURPOSE

- This MAPP describes policies and procedures for the publication and use of good review practices (GRPs) within the Center for Drug Evaluation and Research (CDER).

BACKGROUND

- A **good review practice (GRP)** is a *documented best practice* within CDER that discusses any aspect related to the process, format, content, and/or management of a product review. GRPs are developed over time as superior practices based on CDER's collective experience to provide consistency to the overall review process of new products. GRPs are developed to improve the quality of reviews and review management. GRPs improve efficiency, clarity, and transparency of the review process and review management. GRPs are expected to be adopted by review staff as standard processes through supervisor mentoring, implementation teams, and formal training when necessary.

- Developing GRPs is an attempt to identify, collect, enhance, implement, and adopt many of these best practices as documented and standardized GRPs that can be shared among all review divisions. Many GRPs are initiated based on experiences within individual review divisions. GRPs are also developed within CDER either as responses to changing regulatory environments (e.g.,

the Prescription Drug User Fee Act) or as ongoing efforts to improve and standardize internal processes across review divisions, including quality systems implementation. However, there are still best practices that remain undocumented and that have not been developed into GRPs.

- Until now, there was no consistent method of documenting GRPs in CDER. GRPs were developed as either guidances for review staff or as manuals of policies and procedures (MAPPs). For example, the GRPs for conducting and documenting a clinical safety review of a marketing application and for the format of the pharmacology and toxicology review are described in guidances for review staff.[1] The GRPs for conducting and documenting the clinical and clinical pharmacology reviews are described in MAPPs.[2]

- We believe developing and documenting GRPs in a consistent manner may address problems with review processes and enhance review practices across CDER. For example, in the aforementioned MAPP 6010.3 *Good Review Practice: Clinical Review Template*, CDER developed a standard clinical review template in response to the lack of documented general principles underlying the format and content of a new drug application review. MAPP 6010.3 was also created to ensure reviews are comprehensive and that all reviews contain predictable headings and subheadings.

- As GRPs are developed, review staff need to be able to access them and adopt them into their daily review activities. Since GRPs can change and evolve frequently as a result of new science, statutes, regulations, guidances, and accumulated experience, GRP policies are expected to be updated regularly.

FUNDAMENTAL VALUES

- All GRPs share fundamental values that make them exceptional and require them to be disseminated and adopted by review staff. These fundamental values are *quality*, *efficiency*, *clarity*, *transparency*, and *consistency*. These values are consistent with the fundamental values that are discussed in the guidance for review staff and industry *Good Review Management Principles*

[1] See reviewer guidance *Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review* and guidance for reviewers *Pharmacology/Toxicology Review Format*, respectively (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm).

[2] See MAPP 6010.3 *Good Review Practice: Clinical Review Template* and MAPP 4000.4 *Clinical Pharmacology and Biopharmaceutics Review Template*, respectively (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm).

and Practices for PDUFA Products.[3] Fundamental values for all GRPs are summarized below.

- **Quality** — Consistent implementation of GRPs by review staff will enhance the quality of reviews, the review process, and the resultant regulatory action.

- **Efficiency** — GRPs will improve the efficiency of the review process through standardization.

- **Clarity** — GRPs support clarity throughout the review process, including critical review and decision activities that must be completed before a regulatory decision is made.

- **Transparency** — Developing and documenting GRPs ensures that our review processes are readily available in one location via the Internet (through CDER's Web site) to sponsors and the public.

- **Consistency** — By offering a consistent approach and only deviating from it when appropriate (after supervisory concurrence), GRPs help reviewers achieve consistency with their reviews and provide standard review processes across divisions and offices.

POLICY

- GRPs will be followed by review staff when conducting their application reviews.

- Documents that contain GRPs only will be considered MAPPs and will follow the standard clearance process for MAPPs. All new GRP MAPP titles will begin with the following wording: *Good Review Practice.*

- Documents that contain both GRPs and guidance for industry will continue to be issued as guidances for review staff and industry, but will be subtitled *Good Review Practice*, and will follow the standard clearance process for guidances. These guidances will contain the following standard language:

  "Although guidance documents do not legally bind FDA, review staff may depart from guidance documents only with appropriate justification and supervisory concurrence."

[3] We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

- Team leaders and supervisors will ensure that review staff follow GRPs.

- All GRPs will be maintained on the GRP Web site at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm118777.htm.

RESPONSIBILITIES AND PROCEDURES

- Review staff are expected to become thoroughly familiar with pertinent GRPs and to adhere to these GRPs when conducting their reviews unless a particular part of a GRP is not applicable to a particular review or the review staff receive supervisory instruction to do otherwise. The approving supervisor should separately document his or her reason for such a deviation in the electronic or paper document archive associated with that application.

- Team leaders and supervisors will ensure that GRPs are followed, and will provide specific instructions to deviate from the GRPs only when appropriate. Team leaders and supervisors will also mentor reviewers and provide appropriate instruction to review staff regarding content and policy within GRPs.

- CDER will provide appropriate training courses and implementation teams when needed to inform review staff, team leaders, and supervisors of the content and policies contained in GRPs.

- GRPs will be updated regularly with input from the appropriate CDER staff as needed. The updated GRPs will be posted to the GRP Web site after clearance.

- The Quality Management Staff will administer the GRP Web site.

EFFECTIVE DATE

This MAPP is effective upon date of publication.